



EXPRESS MAIL NO. EL773187186US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Tony N. Frudakis et al.
Application No. : 09/590,583
Filed : June 8, 2000
For : COMPOSITIONS AND METHODS FOR THE THERAPY AND
DIAGNOSIS OF BREAST CANCER
Docket No. : 210121.419C9
Date : April 5, 2001

Commissioner for Patents
Washington, DC 20231

RESPONSE TO THE NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT
APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID
SEQUENCE DISCLOSURES

Sir:

In response to the Notice to Comply dated February 5, 2001, please find enclosed the following: From PTO/SB/21; a computer diskette containing a copy of the Sequence Listing in computer readable format; a declaration regarding the computer diskette; a copy of the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures.

The enclosed electronic copy of the Sequence Listing includes no new matter that goes beyond the application as originally filed. Applicants respectfully submit that the above-identified application is now in conformance with 37 C.F.R. §§ 1.821.825 and WIPO Standard 25.

Respectfully submitted,

Seed Intellectual Property Law Group PLLC

William T. Christiansen, Ph.D.
Registration No. 44,614

JEP:ljt

Enclosure:

Postcard
Form PTO/SB/21
Computer diskette
Declaration Regarding Computer Diskette
Copy of Notice to Comply

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

Wpn\210121\419c9\seq\419c9.rsp.doc

Raw Sequence Listing Error Summary

ERROR DETECTED SUGGESTED CORRECTION

SERIAL NUMBER: 09/590,583

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

- 1 ☒ Wrapped Nucleics The number/text at the end of each line "wrapped" down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".
- 2 ☐ Wrapped Aminos The amino acid number/text at the end of each line "wrapped" down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".
- 3 ☐ Incorrect Line Length The rules require that a line not exceed 72 characters in length. This includes spaces.
- 4 ☐ Misaligned Amino Acid Numbering The numbering under each 5th amino acid is misaligned. This may be caused by the use of tabs between the numbering. It is recommended to delete any tabs and use spacing between the numbers.
- 5 ☐ Non-ASCII This file was not saved in ASCII (DOS) text, as required by the Sequence Rules.
Please ensure your subsequent submission is saved in ASCII text so that it can be processed.
- 6 ☐ Variable Length Sequence(s) ☐ contain n's or Xaa's which represented more than one residue.
As per the rules, each n or Xaa can only represent a single residue.
Please present the maximum number of each residue having variable length and indicate in the (ix) feature section that some may be missing.
- 7 ☐ PatentIn ver. 2.0 "bug" A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequence(s) ☐. Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence.
- 8 ☐ Skipped Sequences (OLD RULES) Sequence(s) ☐ missing. If intentional, please use the following format for each skipped sequence:
(2) INFORMATION FOR SEQ ID NO:X:
(i) SEQUENCE CHARACTERISTICS:(Do not insert any headings under "SEQUENCE CHARACTERISTICS")
(xi) SEQUENCE DESCRIPTION:SEQ ID NO:X:
This sequence is intentionally skipped

Please also adjust the "(iii) NUMBER OF SEQUENCES:" response to include the skipped sequence(s).
- 9 ☐ Skipped Sequences (NEW RULES) Sequence(s) ☐ missing. If intentional, please use the following format for each skipped sequence.
<210> sequence id number
<400> sequence id number
000
- 10 ☐ Use of n's or Xaa's (NEW RULES) Use of n's and/or Xaa's have been detected in the Sequence Listing.
Use of <220> to <223> is MANDATORY if n's or Xaa's are present.
In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
- 11 ☐ Use of <213>Organism (NEW RULES) Sequence(s) ☐ are missing this mandatory field or its response.
- 12 ☐ Use of <220>Feature (NEW RULES) Sequence(s) ☐ are missing the <220>Feature and associated headings.
Use of <220> to <223> is MANDATORY if <213>ORGANISM is "Artificial" or "Unknown"
Please explain source of genetic material in <220> to <223> section.
(See "Federal Register," 6/01/98, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of new Rules)
- 13 ☐ PatentIn ver. 2.0 "bug" Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing).
Instead, please use "File Manager" or any other means to copy file to floppy disk.

OIPE

RAW SEQUENCE LISTING
 PATENT APPLICATION: US/09/590,583

DATE: 06/19/2000
 TIME: 10:55:27

Input Set : A:\419c9.app
 Output Set: N:\CRF3\06192000\I590583.raw

Does Not Comply
 Corrected Diskette Needed

3 <110> APPLICANT: Frudakis, Tony N.
 4 Reed, Steven G.
 5 Smith, John M.
 6 Misher, Linda E.
 7 Dillon, Davin C.
 8 Retter, Marc W.
 9 Wang, Aijun
 10 Skeiky, Yasir A.W.
 12 <120> TITLE OF INVENTION: COMPOSITIONS AND METHODS FOR THE
 13 THERAPY AND DIAGNOSIS OF BREAST CANCER
 16 <130> FILE REFERENCE: 210121.419C9
 C--> 18 <140> CURRENT APPLICATION NUMBER: US/09/590,583
 19 <141> CURRENT FILING DATE: 2000-06-08
 22 <160> NUMBER OF SEQ ID NOS: 324
 24 <170> SOFTWARE: FastSEQ for Windows Version 3.0

ERRORED SEQUENCES

1109 <210> SEQ ID NO: 59
 1110 <211> LENGTH: 208
 1111 <212> TYPE: DNA
 1112 <213> ORGANISM: Homo sapien
 1114 <400> SEQUENCE: 59
 1115 gctcctcttg ccttaccacac ttgacacca tcatcaacca tgtggccagg ttgcagccc 60
 E--> 1116 aggctgcaca tcaggggact gctcgcgaat acttcatgct gttgctgctg actgatggtg 120ctgtgacgga tgtggaagcc acacgtgagg ct;
 1117 cagtcatcat tatgggtggt aatgget 208
 2369 <210> SEQ ID NO: 151
 2370 <211> LENGTH: 323
 2371 <212> TYPE: DNA
 2372 <213> ORGANISM: Homo sapien
 2374 <220> FEATURE:
 2375 <221> NAME/KEY: misc_feature
 2376 <222> LOCATION: (1)...(323)
 2377 <223> OTHER INFORMATION: n = A,T,C or G
 2379 <400> SEQUENCE: 151tnacgcngcn acnntgtaga ganggnaagg cnttccccac attnccccctt catnanagaa 60
 E--> 2380 ttattcnacc aagmntgacc natgcenttt atgacttaca tgcnnactnc ntaatctgtn 120
 E--> 2381 tcnngcctta aaagcnnntc cactacatgc ntcancactg tntgtgtnac ntcatnaact 180
 E--> 2382 gtengnaata ggggcnacata actacagaaa tgcanttcac actgcttcca ntgccatcng 240
 E--> 2383 cgtgtggcct tncctactct tcttntatc caagtagcat ctctggantg cttccccact 300
 E--> 2384 ctccacattg ttgcagcnat aat 323
 4835 <210> SEQ ID NO: 295
 4836 <211> LENGTH: 1853
 4837 <212> TYPE: DNA
 4838 <213> ORGANISM: Homo sapien
 4840 <400> SEQUENCE: 295
 4841 gggtcgcca ggggsgcgt gggcttctc cgggtgggtg tgggttttcc ctgggtgggg 60

See #1 on
 Error Summary
 Sheet

RAW SEQUENCE LISTING
PATENT APPLICATION: US/09/590,583

DATE: 06/19/2000
TIME: 10:55:28

Input Set : A:\419c9.app

Output Set : N:\CRF3\06192000\I590583.raw

4842	tgggctgggc	trgaatcccc	tgctgggggt	ggcaggtttt	ggctgggatt	gacttttytc	120
4843	ttcaaacaga	ttggaaaccc	ggagttacct	gctagttggt	gaaactgggt	ggtagacgcg	180
4844	atctgttgcc	tactactggc	ttctcctggc	tgtaaaagc	agatgggtgt	tgaggttgat	240
4845	tccatgccgg	ctgcttcttc	tgtgaagaag	ccatttggtc	tcaggagcaa	gatgggcaag	300
4846	tggtgctgcc	gttgcttccc	ctgctgcagg	gagagcggca	agagcaacgt	gggcacttct	360
4847	ggagaccacg	acgactctgc	tatgaagaca	ctcaggagca	agatgggcaa	gtggtgccgc	420
4848	cactgcttcc	cctgctgcag	ggggagtggc	aagagcaacg	tgggcgcttc	tggagaccac	480

See #1 Summary
on "Error Sheet"

E--> 4849

gacgagtctg ctatgaagac actcaggaac aagatgggca agtgggtgctg ccactgcttc 540ccctgctgca gggggagcrg caagagcaag gtc

4850	gccttcctgg	akcccaggta	ccacgbeert	ggagaagatc	tggaacagct	ccacagagct	660
4851	gcctgggtggg	gtaaagtccc	cagaaaggat	ctcatcgtca	tgctcagggc	cackgaygtg	720
4852	aacaagargg	acaagcaaaa	gaggactgct	ctacatctgg	cctctgccaa	tggaattca	780
4853	gaagtagtaa	aactcstgct	ggacagacga	tgtcaactta	atgtccttga	caacaaaaag	840
4854	aggacagctc	tgayaaaggg	cgtacaatgc	caggaagatg	aatgtgcggt	aatgttgctg	900
4855	gaacatggca	ctgatccaaa	tattccagat	gagtatggaa	ataccactct	rcactaygct	960
4856	rtctayaatg	aagataaatt	aatggccaaa	gcactgctct	tatayggtgc	tgatatcgaa	1020
4857	tcaaaaaaca	agcatggcct	cacaccactg	ytacttggtr	tacatgagca	aaaacagcaa	1080
4858	gtsgtgaaat	ttttaatyaa	gaaaaaagcg	aatttaaaat	gcrctggata	gatattggaag	1140
4859	ractgctctc	atacttgcct	tatgttggg	atcagcaagt	atagtcagcc	ytctacttga	1200
4860	gcacaaatrtt	gatgtatctt	ciccaagatct	ggaaagacgg	ccagagagta	tgctgtttct	1260
4861	agtcacatc	atgtaatttg	ccagttactt	tctgactaca	aagaaaaaca	gatgttaaaa	1320
4862	atctcttctg	aaaacagcaa	tccagaacaa	gacttaaaagc	tgacatcaga	ggaagagtca	1380
4863	caaaggctta	aaggaagtga	aaacagccag	ccagaggcat	ggaaactttt	aaatttaaac	1440
4864	ttttggttta	atgttttttt	tttttgcctt	aataatatta	gatagtccca	aatgaaatwa	1500
4865	cctatgagac	taggctttga	gaatcaatag	attctttttt	taagaatctt	ttggctagga	1560
4866	gcggtgtctc	acgcctgtaa	ttccagcacc	ttgagaggct	gaggtgggca	gatcacgaga	1620
4867	tcaggagatc	gagaccatcc	tggtctaacac	ggtgaaaccc	catctctact	aaaaatacaa	1680
4868	aaacttagct	gggtgtggtg	gcgggtgcct	gtagtccag	ctactcagga	rgctgaggca	1740
4869	ggagaatggc	atgaaccggg	gaggtggagg	ttgcagttag	ccgagatccg	ccactacact	1800
4870	ccagcctggg	tgacagagca	agactctgtc	tcaaaaaaaaa	aaaaaaaaaaa	aaa	1853

5564 <210> SEQ ID NO: 315

5565 <211> LENGTH: 293

5566 <212> TYPE: PRT

5567 <213> ORGANISM: Homo sapiens

5569 <400> SEQUENCE: 315

5570	Met	His	Leu	Ser	Phe	Pro	Ala	Phe	Leu	Pro	Pro	Trp	Met	Asp	Arg	Gly
5571					5					10					15	
5573	Ser	Gly	Lys	Ser	Asn	Val	Gly	Thr	Ser	Gly	Asp	His	Asn	Asp	Ser	Ser
5574					20					25					30	
5576	Val	Lys	Thr	Leu	Gly	Ser	Lys	Arg	Cys	Lys	Trp	Cys	Cys	His	Cys	Phe
5577					35					40					45	
5579	Pro	Cys	Cys	Arg	Gly	Ser	Gly	Lys	Ser	Asn	Val	Val	Ala	Trp	Gly	Asp
5580					50					55					60	
5582	Tyr	Asp	Asp	Ser	Ala	Phe	Met	Asp	Pro	Arg	Tyr	His	Val	His	Gly	Glu
5583					65					70					75	
5585	Asp	Leu	Asp	Lys	Leu	His	Arg	Ala	Ala	Trp	Trp	Gly	Lys	Val	Pro	Arg
5586					85					90					95	
5588	Lys	Asp	Leu	Ile	Val	Met	Leu	Arg	Asp	Thr	Asp	Val	Asn	Lys	Arg	Asp
5589					100					105					110	
5591	Lys	Gln	Lys	Arg	Thr	Ala	Leu	His	Leu	Ala	Ser	Ala	Asn	Gly	Asn	Ser

RAW SEQUENCE LISTING
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DATE: 06/19/2000
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Input Set : A:\419c9.app
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```

5592      115      120      125
5594 Glu Val Val Lys Leu Val Leu Asp Arg Arg Cys Gln Leu Asn Val Leu
5595      130      135      140
5597 Asp Asn Lys Lys Arg Thr Ala Leu Thr Lys Ala Val Gln Cys Gln Glu
5598 145      150      155      160
5600 Asp Glu Cys Ala Leu Met Leu Leu Glu His Gly Thr Asp Pro Asn Ile
5601      165      170      175
5603 Pro Asp Glu Tyr Gly Asn Thr Thr Leu His Tyr Ala Val Tyr Asn Glu
5604      180      185      190
5606 Asp Lys Leu Met Ala Lys Ala Leu Leu Tyr Gly Ala Asp Ile Glu
5607      195      200      205
5609 Ser Lys Asn Lys His Gly Leu Thr Pro Leu Leu Leu Gly Ile His Glu
5610      210      215      220
5612 Gln Lys Gln Gln Val Val Lys Phe Leu Ile Lys Lys Lys Ala Asn Leu
5613 225      230      235      240
5615 Asn Ala Leu Asp Arg Tyr Gly Arg Thr Ala Leu Ile Leu Ala Val Cys
5616      245      250      255
5618 Cys Gly Ser Ala Ser Ile Val Ser Pro Leu Leu Glu Gln Asn Val Asp
5619      260      265      270
5621 Val Ser Ser Gln Asp Leu Glu Arg Arg Pro Glu Ser Met Leu Phe Leu
5622      275      280      285
5624 Val Ile Ile Met
E--> 5625      290

```

Length of 293 listed, actual count 292

✓ F.Y.I.

Please Note:

Use of n and/or Xaa have been detected in the Sequence Listing. Please review the Sequence Listing to ensure that a corresponding explanation is presented in the <220> to <223> fields of each sequence which presents at least one n or Xaa.

VERIFICATION SUMMARY
PATENT APPLICATION: US/09/590,583DATE: 06/19/2000
TIME: 10:55:29Input Set : A:\419c9.app
Output Set: N:\CRF3\06192000\I590583.raw

OK
L:85 M:270 C: Current Application Number differs, Wrong Format
L:85 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:3
L:86 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:3
L:87 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:3
L:88 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:3
L:89 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:3
L:90 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:3
L:91 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:3
L:113 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:4
L:114 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:4
L:115 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:4
L:116 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:4
L:117 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:4
L:118 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:4
L:119 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:4
L:120 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:4
L:121 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:4
L:122 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:4
L:140 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:5
L:141 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:5
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L:149 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:5
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L:151 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:5
L:167 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:6
L:168 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:6
L:169 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:6
L:170 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:6
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L:200 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:7
L:203 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:7
L:204 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:7
L:205 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:7
L:206 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:7

VERIFICATION SUMMARY DATE: 06/19/2000
PATENT APPLICATION: US/09/590,583 TIME: 10:55:29

Input Set : A:\419c9.app
Output Set: N:\CRF3\06192000\I590583.raw

L:207 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:7
L:208 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:7
L:209 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:7
L:1116 M:320 E: (1) Wrong Nucleic Acid Designator, NUMBER OF INVALID KEYS:3
L:2380 M:254 E: No. of Bases conflict, LENGTH:Input:120 Counted:60 SEQ:151
M:254 Repeated in SeqNo=151
L:2384 M:252 E: No. of Seq. differs, <211>LENGTH:Input:323 Found:263 SEQ:151
L:4849 M:320 E: (1) Wrong Nucleic Acid Designator, NUMBER OF INVALID KEYS:3
L:5625 M:252 E: No. of Seq. differs, <211>LENGTH:Input:293 Found:292 SEQ:315